



Virginia
Regulatory
Town Hall

Periodic Review and Retention of Existing Regulations Agency Background Document

Agency Name:	Agriculture and Consumer Services (Board of)
VAC Chapter Number:	2 VAC 5-490
Regulation Title:	Regulations Governing Grade "A" Milk
Action Title:	Review
Date:	February 4, 2000

This information is required pursuant to the Administrative Process Act § 9-6.14:25, Executive Order Twenty-Five (98), and Executive Order Fifty-Eight (99) which outline procedures for periodic review of regulations of agencies within the executive branch. Each existing regulation is to be reviewed at least once every three years and measured against the specific public health, safety, and welfare goals assigned by agencies during the promulgation process.

This form should be used where the agency is planning to retain an existing regulation.

Summary

Please provide a brief summary of the regulation. There is no need to state each provision; instead give a general description of the regulation and alert the reader to its subject matter and intent.

The regulation establishes: (1) the requirements to produce and sell Grade "A" milk for pasteurization; (2) the requirements to process and sell fluid milk products (milk, yogurt, and cottage cheese); (3) that milk used for Grade AA@ purposes be pasteurized; (4) the requirement for a permit to produce or process Grade AA@ milk; and (5) minimum standards that dairy farms and dairy plants must meet in producing and processing Grade AA@ milk, including pasteurization, cooling, storage, quality-control tests, packaging, and labeling requirements.

Basis

Please identify the state and/or federal source of legal authority for the regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. Where applicable, explain where the regulation exceeds the minimum requirements of the state and/or federal mandate.

Sections 3.1-530.1 and 3.1-530.2 of the Code of Virginia (1950), as amended, provide the statutory authority for the regulation. These sections do not require the Board of Agriculture and Consumer Services to adopt regulations governing grade "A" milk and milk products.

Public Comment

Please summarize all public comment received as the result of the Notice of Periodic Review published in the Virginia Register and provide the agency response. Where applicable, describe critical issues or particular areas of concern in the regulation. Also please indicate if an informal advisory group was formed for purposes of assisting in the periodic review.

The Department published its notice in The Virginia Register of Regulations on November 8, 1999 advertising the opportunity to comment on this regulation pursuant to Executive Order Number Twenty-five (98). An informal advisory group was not formed for the purpose of assisting with this periodic review.

The agency received comments from the Virginia State Dairymen's Association, Maryland and Virginia Milk Producers Association, and the Extension Milk Quality Leadership Council. These organizations taken together represent a broad cross section of the dairy industry in Virginia including, dairy farmers, milk marketing cooperatives, dairy processors, dairy extension leaders, educators, bankers, and financiers. Each of these organizations recommended that the agency adopt the latest version of the Grade "A" Pasteurized Milk Ordinance -- 1978 recommendations of the United States Public Health Service/Food and Drug Administration (PMO), 1978 Edition (1999 revision) as soon as possible. The PMO forms the basis for grade "A" milk regulation in all the states within the United States. Significant changes made to the PMO this year included: (i) the elimination of required two and four day suspension periods for violation of the animal drug-residue standards; (ii) acceptance of the imposition of a civil penalty in lieu of permit suspension; and (iii) the creation of a new nationally uniform program that requires all persons weighing and sampling milk, as well as all tank trucks used to transport milk, to have a permit and be evaluated at least every two years.

The agency agrees that the changes made to the PMO should be adopted in Virginia. However, the revised PMO in its final form does not exist at this time. Until the revised PMO is published, the agency cannot proceed to adopt the changes into Virginia regulation.

The agency received comments from the Virginia State Dairymen's Association and the Extension Milk Quality Leadership Council concerning the agency's inability to adopt the most recent revision of the PMO in a timely manner. Each of these organizations recommended that the agency be exempted from the Administrative Process Act (APA) and allowed to adopt regulations by reference and under an expedited regulation-making process that would allow revised regulations to be adopted shortly after the publication of any newly revised PMO. The issue of exemptions from the APA is not within the purview of the agency or the regulatory review process.

The agency received comments from the Virginia State Dairymen's Association and the Extension Milk Quality Leadership Council recommending the agency be allowed to impose civil penalties in order to take advantage of recent changes in the PMO allowing for civil penalties to substitute for permit suspension actions. According to John Miller, Secretary of the Virginia State Dairymen's Association, the ability to substitute civil penalties for permit suspension would allow dairy producers the opportunity to eliminate adulterated milk from the marketplace and begin shipping Grade A milk sooner. The issue of civil penalty authority is not within the purview of the agency or the regulatory review process.

Effectiveness

Please provide a description of the specific and measurable goals of the regulation. Detail the effectiveness of the regulation in achieving such goals and the specific reasons the agency has determined that the regulation is essential to protect the health, safety or welfare of citizens. Please assess the regulation's impact on the institution of the family and family stability. In addition, please indicate whether the regulation is clearly written and easily understandable by the individuals and entities affected.

The regulation is effective in achieving its specific and measurable goals.

The first specific goal of the regulation is to reduce the risk of death and illness from consuming contaminated Grade "A" milk and milk products. This is accomplished through the requirement of pasteurization as an effective means of destroying pathogens in Grade "A" milk and milk products. The regulation also requires plants to employ certain practices that prevent contamination after pasteurization has occurred. According to the Virginia Department of Health, Office of Epidemiology, there were 968 individuals with confirmed cases of foodborne illness reported in Virginia during 1997 (most current data available). Without the mechanisms established in this and other regulations designed to protect against the contamination of food, the number of foodborne illnesses in the Commonwealth probably would be considerably higher.

The second specific goal of the regulation is to facilitate sales of Virginia-manufactured dairy products in intrastate and interstate commerce. Grade "A" milk and milk products are regulated and marketed throughout the United States under a system based on the PMO. One provision of the PMO requires that only Grade "A" milk and milk products produced in compliance with the provisions of the recommended requirements be marketed within any state that has adopted the PMO or in interstate commerce. Without regulations that are "substantially equivalent" to the

PMO, Virginia Grade "A" dairy producers and processors would be limited to intrastate sales only. The regulation is essential to maintain the economic viability of Virginia's dairy producers and processors.

Sales of Virginia-manufactured dairy products are facilitated by fostering the safe and wholesome image grade "A" dairy products enjoy with consumers. Historically, sales of dairy products are very sensitive to reports of illness associated with its consumption or instances of adulteration. The regulation seeks to eliminate illness outbreaks and instances of adulteration by establishing minimum quality standards, labeling and packaging requirements for all grade "A" milk products. These minimum standards create products which are readily identified and trusted by consumers. Without the regulation consumers would not be confident that the dairy products they purchase and consume are safe, wholesome, and nutritious.

The regulation is clearly written and easily understood by the individuals and entities affected.

Alternatives

Please describe the specific alternatives for achieving the purpose of the existing regulation that have been considered as a part of the periodic review process. This description should include an explanation of why such alternatives were rejected and this regulation reflects the least burdensome alternative available for achieving the purpose of the regulation.

The agency has considered, during the course of this review, the following alternatives.

The first alternative considered is to promulgate exemptions to the regulation which would allow the sale of unpasteurized goats' milk directly to consumers in Virginia. Frequent reasons cited in favor of allowing an exemption for both on-the-farm sales and off-the-farm sales of unpasteurized goats' milk include:

1. Individual citizens should be allowed to choose whether or not they consume unpasteurized milk;
2. Only small quantities of goats' milk would be sold to those persons seeking it out for their own consumption; and
3. Unpasteurized goats' milk is needed by some people for health reasons.

The agency rejects these arguments as justification to allow the sale of unpasteurized goats' milk for human consumption for the following reasons:

1. The consumption of unpasteurized milk is associated with numerous disease outbreaks in the United States and represents a significant public health risk;

2. The Code of Federal Regulations, Chapter 21 CFR §131.110, prohibits the sale of unpasteurized milk in interstate commerce;
3. The process of pasteurization eliminates any pathogens present in the milk at the time of pasteurization and significantly reduces the risk of illness to consumers of milk and milk products;
4. The economic advantages to those persons who would sell unpasteurized milk are relatively small compared to: (i) the significant negative impact on the sales of Virginia-produced milk and milk products in the event of a disease outbreak associated with the consumption of unpasteurized milk; and (ii) the health of even one Virginia citizen;
5. Not all of Virginia's citizens will have a choice in whether to consume unpasteurized milk. Children in particular will not have a choice because they will consume unpasteurized milk if it is provided for them by adults and relatives responsible for their care;
6. The assertion that only limited amounts of unpasteurized milk will be sold on the farm in no way limits the risk of illness associated with the consumption of unpasteurized milk. If the unpasteurized milk is contaminated with pathogens, the consumer may become ill, although little milk is consumed;
7. The agency acknowledges that there are health related reasons for persons to consume goats' milk rather than cows' milk; however, there is no scientific evidence which demonstrates any significant nutritional difference between unpasteurized milk and pasteurized milk. Pasteurized cows' and goats' milk is readily available in stores throughout the Commonwealth. Considering the availability of pasteurized milk and milk products of known safety, there is not sufficient justification to allow the sale of unpasteurized milk and milk products for human consumption.

The second alternative considered is not to regulate Grade "A" milk at all. This alternative was rejected for the following reasons:

1. Pasteurization is important to public health and the current regulation requires pasteurization,
2. Consumer confidence in the wholesomeness of milk and milk products would not be enhanced; and
3. Virginia Grade "A" milk producers and processors would be denied access to markets outside the Commonwealth.

A third alternative considered is to place the burden of complying with the recommended requirements of the PMO on the dairy industry in Virginia with supervision of the industry program provided by the agency. This alternative was rejected for the following reason:

1. Public health and safety are government responsibilities. The highest level of consumer protection and confidence in milk and milk products could not be achieved by a program implemented and administered by industry self-regulation.

It is recommended that this regulation continue to be enforced through the regulatory services of the Department of Agriculture and Consumer Services and the Virginia Department of Health for the following reasons:

1. Current programs operated by the Department of Agriculture and Consumer Services and the Department of Health working cooperatively provide the highest level of consumer protection and confidence in the safety and wholesomeness of milk and milk products;
2. Programs operated and administered by the two agencies provide for the most efficient and uniform application of inspection and quality standards in Virginia;
3. Food safety programs benefit every person in Virginia and are an important and appropriate role of state government; and
4. The current regulation was strongly supported by Grade "A" dairy farmers, milk marketing cooperatives, the Virginia State Dairymen's Association, and the Virginia Department of Health, for adoption by the Board of Agriculture and Consumer Services when it was adopted in 1993.

Recommendation

Please state that the agency is recommending that the regulation should stay in effect without change.

The agency recommends that the regulation be retained in its current form. The agency acknowledges that there have been significant changes to the requirements contained in the PMO; however, this document does not yet exist. Until the Food and Drug Administration publishes a revised edition of the PMO, the agency will be unable to: (i) propose or adopt a regulation containing the revised PMO; or (ii) file a proposed or final regulatory package containing the revised PMO with the Registrar of Regulations. The agency will revisit and review the regulation again after the publication of the PMO.

Family Impact Statement

Please provide an analysis of the regulation's impact on the institution of the family and family stability including the extent to which it: 1) strengthens or erodes the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourages or discourages economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children

and/or elderly parents; 3) strengthens or erodes the marital commitment; and 4) increases or decreases disposable family income.

Unless otherwise discussed in this report, this regulation has no impact upon families.